DIA:Information Technology Initiatives in Drug Registration Systems:

Electronic Submissions in CBER

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CBER

CBER 2004
Strategic Goals

- A managed and integrated regulatory process from discovery through post marketing
- A high quality research program which contributes directly to the regulatory mission
- A high quality and diverse work force
- Interactive information systems which are integral to all CBER activities
- Leveraged resources

Goal: A managed and integrated regulatory process which is continuous from discovery through post-marketing

Strategies:

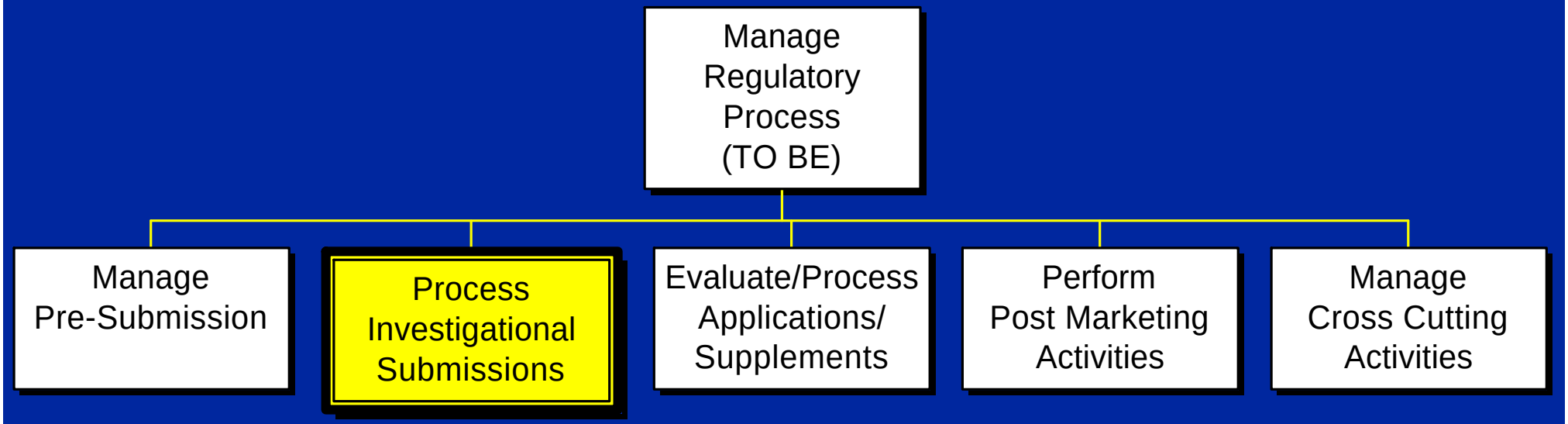
- Apply the concepts of managed review to the entire regulatory process
- Continually improve the regulatory process
- Assure an accountable management that promotes teamwork at all staff levels

Project Plan

- Develop a business model of CBER's regulatory process - DONE
- Identify weaknesses/bottlenecks in the current regulatory process - DONE
- Propose and evaluate solutions to overcome these weaknesses/bottlenecks - DONE
- Design a new, streamlined Managed Review Process (MRP) - DONE
- Identify performance goals in order to expand the MRP (in Progress)

Manage Regulatory Process

A Managed and Integrated Regulatory Process Which is Continuous from Discovery Through Post Marketing



Phase 1

C B
E R

Goal: Interactive information systems are integral to all CBER activities

Strategies:

- Fully integrate information systems to support a seamless regulatory process
- Support the development and use of interactive databases
- Capitalize on information related initiatives outside of CBER

Significant Accomplishments in Information Technology

- Desktop Standardization
- Electronic Submissions - BLAs, INDs
- Document Management Technology
- Regulatory Management System
- Electronic Lot Release (note: 26% reduction in Review Days)

Legislative Background for e-Submissions

- PDUFA I - 1992
- FDA Submisison Management and Review Tracking Program (SMART) Program - 1994
- REGO Initiatives- 1995

C B
E R

Legislative Background for e-Submissions

- Paper Reduction Act- 1995
- Electronic FOI Act- 1996
- e-Records: e-Signatures Reg 21CFR11- 1997
- FDA Modernization Act - 1997/ PDUFA II- 1997

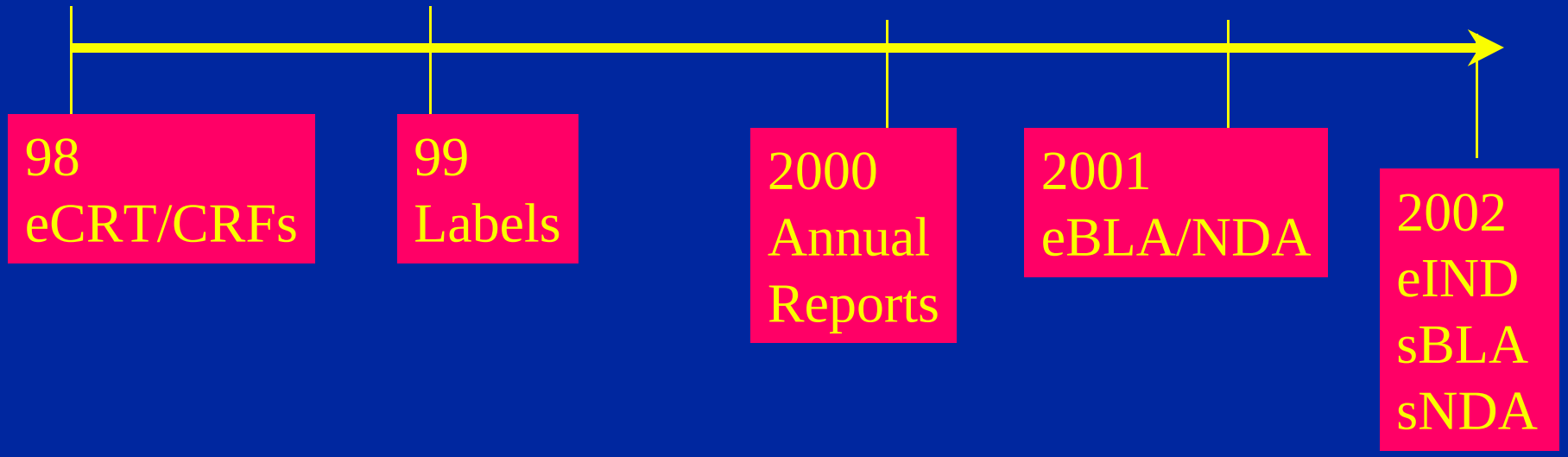
C B
E R

FDA Modernization Act

- **Section G of the Act:**
  - **Update IT Infrastructure**
  - **eINDs by 2002**
- **PDUFA II commitments**

C B
E R

PDUFA II Timeline



For Electronic Submissions

C B
E R

CBER Operating Principles/Preferences

- Electronic archive copy = electronic review copy (No field or desk copies)
- Archival and review interim standards:
  - PDF for text/documents
  - SAS for data
- We discourage customized submissions or reviewer electronic aids
- We discourage sponsor supplied hardware and software

Difficulties with Customized CALAs

- Conflicts with other applications and LAN
- Reviewer cannot leverage reuse of what is learned
- Archive and retrieval problems
- Difficult to respond to eFOIA requests
- Validation problems between paper CRTs, customized submissions, SAS datasets

Standardizing the Electronic Format

- The harmonized FDA Form 356h for the eBLA
- Form 1571 and 1572 for the eIND
- Adobe PDF Format for Text
- SAS files for Data

Projects we are working on for a successful e-Submissions Program

- **Functional eDCC/Library**
- **E-mail to exchange complex documents and data files (e.g., PDF, SAS).**
- **LAN servers with back-ups**
- **Robust Center networks**

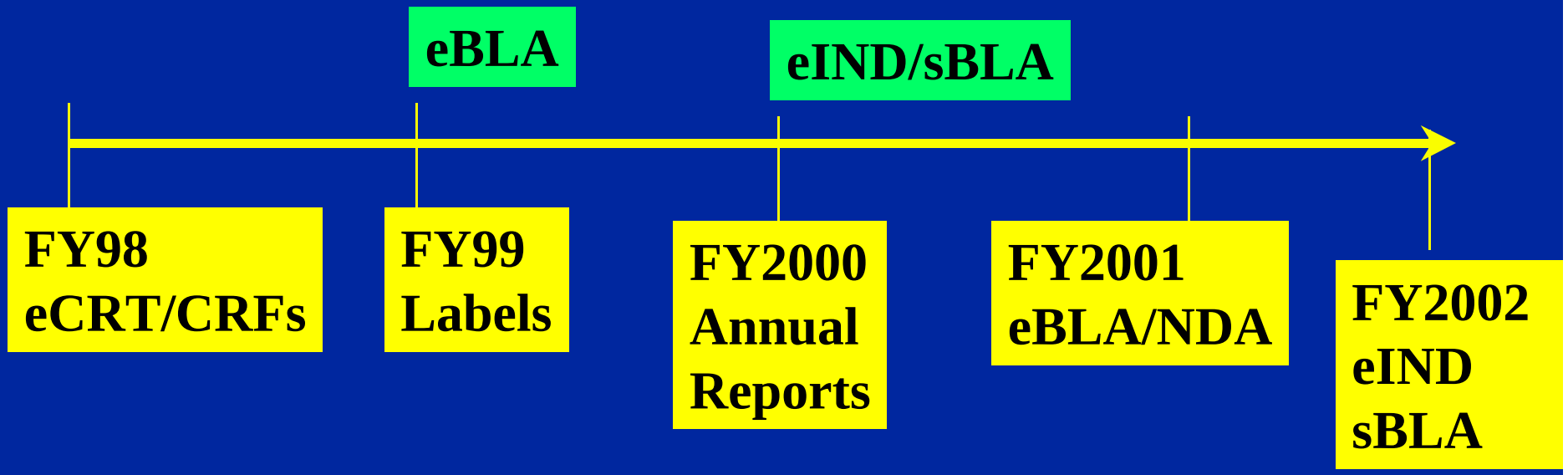
Projects we are working on for a successful e-Submissions Program

- Training for Adobe Exchange, JMP, application help teams
- Dual monitors for some reviewers
- Documents for licensed review (letters, reviews, labels, SBAs) need to be available electronically for eFOIA and AERS

Approaches to Paper-less Receipt of Applications

- **Approach I: Issue guidance for receipt of entire application**
  - **current CBER approach**
- **Approach II: Issue guidance incrementally**

Approach I.
Meeting or Beating the Deadlines



For Electronic Submissions

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